



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0473; FRL-9913-38]

Registration Review Proposed Interim Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed interim registration review decisions and opens a public comment period on the proposed interim decisions. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit II.A., by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact:* The Chemical Review Manager for the pesticide of interest identified in the table in Unit II.A.

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8015; email address: *dumas.richard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the table in Unit II.A.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for the pesticides shown in the table in this unit, and opens a 60-day public comment period on the proposed interim decisions.

1. *Acetaminophen (proposed interim decision)*. The registration review docket for acetaminophen (EPA-HQ-OPP-2012-0145) opened in a notice published in the **Federal Register** of March 28, 2012 (77 FR 18810) (FRL-9342-1). Acetaminophen is registered for use as a vertebrate pesticide to control the invasive brown tree snake in Guam. The snakes ingest baited mice, which are lethal to the snake. There are no registered food/feed uses for acetaminophen. No pesticide tolerances have been established. EPA did not conduct a human health risk assessment because acetaminophen's pharmaceutical use is well-studied and opportunities for exposure from its pesticidal use are extremely limited. The Agency conducted a quantitative ecological risk assessment for acetaminophen. Baited mice are not likely to be consumed or consumed in quantity by resident animals other than the brown tree snake, the acetaminophen in the mice is not likely to end up in aquatic environments, and there is little potential for exposure to plants. The Agency has concluded that there are no risks of concern for native, non-target organisms associated with the pesticidal use of acetaminophen. The Agency has made a "no effect" determination for all federally listed species and a "no adverse modification of critical habitat" determination. Acetaminophen has not been evaluated under the Endocrine Disruptor Screening Program (EDSP). Therefore, the Agency's final registration review decision is dependent on the results of the evaluation of potential endocrine disruptor risks. Pending the outcome of this action, EPA is planning to issue an interim registration review decision for acetaminophen.

2. *Clofentezine (proposed interim decision)*. The registration review docket for clofentezine (EPA-HQ-OPP-2006-0240) opened in a notice published in the **Federal Register** of March 28, 2007 (72 FR 14548) (FRL-8118-3). Clofentezine is an acaricide registered for use to control mites. It is a liquid formulation for use on almonds, apples, apricots, cherries, Christmas trees, grapes (except New York), nectarines, ornamentals (greenhouse and outdoor), peaches, pears, persimmons, and walnuts. There are currently no registered residential uses of clofentezine. Based on the human health risk assessment conducted in support of registration review for clofentezine, the Agency determined that there are no human health risks of concern for the currently registered uses of clofentezine. Based on the ecological risk assessment that was completed in support of registration review for clofentezine, EPA has determined that all

outdoor uses of clofentezine can potentially lead to direct adverse effects to listed and non-listed birds.

The chronic risk level of concern (LOC) was exceeded by dietary risk quotients (RQs) for birds. As birds serve as surrogates to reptiles and terrestrial-phase amphibians, risk to these taxa is also a possibility. The chronic risk to mammals is uncertain and is expected to be limited. The dose-based risk assessment concludes that the chronic RQs slightly exceeds the chronic LOC for small to medium mammals feeding exclusively on short grass, but this was based on a study which showed no effects to growth, reproduction, or survival at the highest dose tested. Clofentezine is moderately persistent in the terrestrial environment and is expected to decline to below toxic levels approximately 1 to 2 weeks after application.

Use of clofentezine is not expected to pose a risk to foraging (adult) bees; however, there is a potential for risk to non-listed and listed terrestrial arthropods because of adverse effects to reproduction and development. Use of clofentezine is not expected to cause direct or indirect adverse effects to non-listed or listed fish, aquatic invertebrates, or aquatic plants. Thus, a “no effect” determination is made for all listed aquatic organisms. Several lines of evidence indicate that clofentezine has low toxicity to plants. Therefore, EPA concludes that use of clofentezine will not pose risk to terrestrial, semi-aquatic (monocots, and dicots) or aquatic plants, and is not expected to harm listed species of plants. Thus, a “no effect” determination is made for all listed plants.

This interim decision does not cover the EDSP component of the clofentezine registration review case. Additionally, the ecological risk assessment for clofentezine did not come to a conclusion of “no effect” to some listed species. Therefore, consultation with the U.S. Fish and Wildlife Service (FWS) on the potential risk of clofentezine to

some listed species will be necessary. The Agency is issuing a proposed interim registration review decision pending the evaluation of potential endocrine disruptor risk and consultation with FWS.

3. *Cyromazine (proposed interim decision)*. The registration review docket for cyromazine (EPA-HQ-OPP-2006-0108) opened in a notice published in the **Federal Register** of March 28, 2007 (72 FR 14548) (FRL-8118-3). Cyromazine is a triazine which acts as an insect growth regulator. Cyromazine is registered for use on several agricultural crops such as beans, peppers, and tomatoes; it is registered for use on indoor ornamentals, and to control flies in manure. There are no residential uses for cyromazine. EPA conducted a human health occupational risk assessment and did not identify any risks of concern. The ecological risk assessment identified potential risks to several taxa including birds, mammals, and bees. To mitigate potential ecological risks, the Agency is proposing to increase the application interval for cyromazine use on potatoes; add label language for the onion seed treatment use; add precautionary label language to reduce risk to bees; use; and, increase the minimum droplet size for aerial applications. The proposed changes will reduce estimated risks, but will not reach a conclusion of “no effect” to listed species. Therefore, consultation with FWS on the potential risk of cyromazine to listed species will be necessary. Cyromazine has not been evaluated under EDSP. Therefore, the Agency's final registration review decision is dependent on the results of consultation under section 7 of the Endangered Species Act (ESA) (16 U.S.C. 1536) with the FWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for cyromazine.

4. *Fosthiazate (proposed interim decision)*. The registration review docket for fosthiazate (EPA-HQ-OPP-2009-0267) opened in a notice published in the **Federal Register** of June 24, 2009 (74 FR 30077) (FRL-8422-4). Fosthiazate is an organophosphate nematicide for use only on tomatoes, via drip irrigation under plastic. There are no residential uses for fosthiazate. EPA conducted a human health dietary and occupational risk assessment for fosthiazate and did not identify any risks of concern. The ecological risk assessment identified potential risks to several taxa including birds, mammals, and soil-bound terrestrial invertebrates. To mitigate potential ecological risks, the agency is proposing to modify the application directions for fosthiazate. The proposed change will reduce estimated risks, but will not reach a conclusion of “no effect” to listed species. Therefore, consultation with FWS on the potential risk of fosthiazate to listed species will be necessary. Fosthiazate has not been evaluated under EDSP. Therefore, the Agency's final registration review decision is dependent on the results of consultation under ESA section 7 with FWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for fosthiazate.

5. *Hexythiazox (proposed interim decision)*. The registration review docket for hexythiazox (EPA-HQ-OPP-2006-0114) opened in a notice published in the **Federal**

Register of February 2, 2007 (72 FR 5050) (FRL-8113-1). Hexythiazox is an acaricide that acts primarily as a mite growth inhibitor/ovicide and is used to control mites. It is registered for use on a variety of agricultural crops, turf, and various residential plants. The Agency conducted a human health risk assessment and did not identify any risks of concern. The ecological risk assessment identified areas of potential risk of uncertainty to terrestrial invertebrates, bees, and chronic risk to fish due to lack of data. The Agency is therefore requiring a bee study to determine any productive effects to pollinators. While chronic risk to fish and non-target invertebrates is uncertain due to data gaps, the potential risks expected to be low due to as hexythiazox is applied only once per year at a low rate and is not highly persistent in the environment. The Agency has completed a partial ESA analysis and is making a no effect determination under the ESA for direct adverse effects to listed mammalian, avian (and reptile surrogates) and aquatic plant (vascular and nonvascular). The analysis for indirect effects to listed species in these taxa or effects to their designated critical habitat has not yet been completed. Therefore, consultation with FWS and the National Marine Fisheries Service (NMFS) (the Services) on the potential risk of hexythiazox to listed species will be necessary. Hexythiazox has not been evaluated under the EDSP. Therefore, the Agency's final registration review decision is dependent on the result of consultation under ESA section 7 with FWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for hexythiazox.

6. *Lactofen (proposed interim decision)*. The registration review docket for lactofen (EPA-HQ-OPP-2005-0287) opened in a notice published in the **Federal Register** of February 2, 2007 (72 FR 5050) (FRL-8113-1). Lactofen is a light dependent peroxidizing herbicide (LDPH) with uses on conifer seedlings, cotton, kenaf, peanuts, and soybean, with State-specific uses on fruiting vegetables, okra, and snap beans. There are no residential uses for lactofen. EPA conducted a human health occupational risk assessment and did not identify any risks of concern. The ecological risk assessment identified potential risks to several different taxa. However, due to the number of conservative assumptions included in the assessment, and additional use and usage information to help characterize potential risks, the Agency is not proposing mitigation changes at this time. The risk assessment for lactofen did not come to a conclusion of "no effect" to listed species. Therefore, consultation with FWS on the potential risk of lactofen to listed species will be necessary. Lactofen has not been evaluated under EDSP. Therefore, the Agency's final registration review decision is dependent on the results of consultation under ESA section 7 with FWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for lactofen.

7. *Macleaya extract (proposed interim decision)*. The registration review docket for macleaya extract (EPA-HQ-OPP-2011-0172) opened in a notice published in the **Federal Register** of March 30, 2011 (76 FR 17646) (FRL-8868-9). *Macleaya extract* is a plant extract of *Macleaya cordata*, and is registered for use only in enclosed commercial greenhouses, as an ornamental plant fungicide for the control of foliar fungal diseases. There are no registered food uses of macleaya extract. EPA completed a qualitative draft human health risk assessment for all macleaya extract uses. No risks of concern were identified. The Agency also conducted an ecological risk assessment and endangered species effects determination. No risks of concern were identified and the Agency has made a “no effect” determination for federally listed species and a “No Habitat Modification” determination for all designated critical habitats under ESA. *Macleaya extract* has not been evaluated under EDSP. Therefore, the Agency's final registration review decision is dependent on the result of the evaluation of potential endocrine disruptor risk. Pending the outcome of this action, EPA is planning to issue an interim registration review decision for macleaya extract.

8. *Quizalofop (proposed interim decision)*. The registration review docket for quizalofop (EPA-HQ-OPP-2007-1089) opened in a notice published in the **Federal Register** of December 19, 2007 (72 FR 71893) (FRL-8342-9). Quizalofop is a selective post-emergence herbicide and appears as two different isomers: Quizalofop-ethyl and quizalofop-*p*-ethyl. Quizalofop-ethyl is a 50/50 racemic mixture of *R*- and *S*-enantiomers and there are no active pesticide registrations of this isomer. Quizalofop is the purified *R*-enantiomer and the pesticidally active isomer. For the Agency's purposes, both isomers will be referred to collectively as quizalofop. Quizalofop is registered to control annual and perennial grasses in various crops including Chinese cabbage, cotton, garlic, grains, legumes, mint, pineapple, soybean, sugar beets, and sunflower. Quizalofop is also used in non-agricultural settings, such as cottonwood and poplar plantations, fencerows, roadsides, and other uncultivated areas. EPA conducted a risk assessment for both human health and ecological risk. No risks of concern were identified in the human health risk assessment. The ecological risk assessment indicated potential risks to amphibians, freshwater fish, non-target monocots, and terrestrial mammals. The Agency is proposing mitigation to reduce spray drift risk to non-target organisms. The ecological risk assessment did not come to a conclusion of “no effect” to listed species, therefore, consultation with FWS on the potential risk of quizalofop to listed species will be necessary. Quizalofop has not been evaluated under EDSP. Therefore, the Agency's final registration review decision is dependent on the result of consultation under ESA section 7 with FWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for quizalofop.

9. *Trinexapac-ethyl (proposed interim decision)*. The registration review docket for trinexapac-ethyl (EPA-HQ-OPP-2008-0657) opened in a notice published in the **Federal Register** of September 15, 2008 (73 FR 53244) (FRL-8381-3). Trinexapac-ethyl is a plant growth regulator registered for use by homeowners and professional applicators to manage growth of barley, grasses grown for seed, oats, sugarcane, triticale, turf grass, and wheat. Turf grass uses include

athletic fields and parks, commercial and residential lawns, golf courses, and sod farms. It is also registered for application around flower beds, ornamental trees, and shrubs.

EPA conducted a human health risk assessment and did not identify any risks of concern. In addition, EPA conducted an ecological risk assessment. Based on low-risk estimates, and the conservative nature of the risk assessment, the Agency does not anticipate ecological risks of concern for assessed taxa from currently registered uses of trinexapac-ethyl. The Agency is not proposing mitigation changes at this time. However, the Agency is proposing that labels clarify the single-maximum application rate for liquid turf end-use products. The risk assessment for trinexapac-ethyl did not come to a conclusion of “no effect” to listed species. Therefore, consultation with the Services on the potential risk of trinexapac-ethyl to listed species will be necessary. Trinexapac-ethyl has not been evaluated under EDSP. Therefore, the Agency's final registration review decision is dependent on the result of consultation under ESA section 7 with FWS and the evaluation of potential endocrine disrupter risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for trinexapac-ethyl.

Table--Registration Review Proposed Interim Decisions

Registration Review Case Name and Number	Pesticide Docket Identification Number	Chemical Review Manager, Telephone Number, Email Address
Acetaminophen (Case 7610)	EPA-HQ-OPP-2012-0145	Bonnie Adler (703) 308-8523 <i>adler.bonnie@epa.gov</i>
Clofentezine (Case 7602)	EPA-HQ-OPP-2006-0240	Wilhelmena Livingston (703) 308-8025 <i>livingston.wilhelmena@epa.gov</i>
Cyromazine (Case 7439)	EPA-HQ-OPP-2006-0108	James Parker (703) 306-0469 <i>parker.james@epa.gov</i>
Fosthiazate (Case 7604)	EPA-HQ-OPP-2009-0267	James Parker (703) 306-0469 <i>parker.james@epa.gov</i>
Hexythiazox	EPA-HQ-OPP-2006-0114	Molly Clayton

(Case 7404)		(703) 603-0522 <i>clayton.molly@epa.gov</i>
Lactofen (Case 7210)	EPA-HQ-OPP-2005-0287	Kelly Ballard (703) 305-8126 <i>ballard.kelly@epa.gov</i>
Macleaya Extract (Case 7024)	EPA-HQ-OPP-2011-0172	Susan Bartow (703) 603-0065 <i>bartow.susan@epa.gov</i>
Quizalofop (Case 7215)	EPA-HQ-OPP-2007-1089	Khue Nguyen (703) 347-0248 <i>nguyen.khue@epa.gov</i>
Trinexapac-ethyl (Case 7228)	EPA-HQ-OPP-2008-0657	Kaitlin Keller (703) 308-8172 <i>keller.kaitlin@epa.gov</i>

The registration review docket for a pesticide includes earlier documents related to the registration review of the case. For example, the review opened with a Summary Document, containing a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the initial docket.

The documents in the dockets describe EPA's rationales for conducting additional risk assessments for the registration review of the pesticides included in the table in Unit II.A., as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. These proposed interim registration review decisions are supported by the rationales included in those documents.

Following public comment, the Agency is planning to issue interim registration review decisions for products containing the pesticides listed in the table in Unit II.A.

The registration review program is being conducted under congressionally mandated timeframes, and EPA recognizes the need both to make timely decisions and to involve the public. Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) required EPA to establish by regulation procedures for reviewing pesticide registrations, originally with a goal of reviewing each pesticide's registration every 15 years to ensure that a pesticide continues to meet the FIFRA standard for registration. The Agency's final

rule to implement this program was issued in the **Federal Register** of August 9, 2006 (71 FR 45720) (FRL-8080-4) and became effective October 10, 2006, and appears at 40 CFR part 155, subpart C. The Pesticide Registration Improvement Act of 2003 (PRIA) was amended and extended in September 2007. FIFRA, as amended by PRIA in 2007, requires EPA to complete registration review decisions by October 1, 2022, for all pesticides registered as of October 1, 2007 (7 U.S.C. 136a(g)).

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed decision. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the table in Unit II.A. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and will provide a "Response to Comments Memorandum" in the docket. The final registration review decision will explain the effect that any comments had on the decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at:
http://www.epa.gov/oppsrrd1/registration_review. Links to earlier documents related to the registration review of these pesticides are provided at:
http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm.

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA (7 U.S.C. 136a(g)) and 40 CFR part 155, subpart C, provide authority for this action.

List of Subjects

Environmental protection, Acetaminophen, Administrative practice and procedure, Clofentezine, Cyromazine, Fosthiazate, Hexythiazox, Lactofen, Macleaya extract, Pesticides and pests, Quizalofop, and Trinexapac-ethyl.

Dated: July 15, 2014.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

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